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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,174	09/01/2005	Ralf Herwig	13027.60USWO	5243
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MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			EXAMINER NATARAJAN, MEERA	
			ART UNIT 1643	PAPER NUMBER
			MAIL DATE 10/15/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/519,174

**Applicant(s)**

HERWIG, RALF

**Examiner**

Meera Natarajan

**Art Unit**

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>03/18/2005</u> . | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Claims 1-6 will be examined on the merits.

#### ***Claim Objections***

2. Claim 1 and 2 are objected to because of the following informalities: Claim 1 recites "peroration" (line 3). Does applicant mean "perforation" of said macrophage cells? Claim 2 recites incorrect spelling of "antibody/ies", correct spelling is antibody/s. Appropriate spelling corrections are required.

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 5 recites the limitation "said staining of PSA" in line 2. There is insufficient antecedent basis for this limitation in the claim. "PSA" is not recited in the dependent claims 4 or 1. Correction is required.
5. Claim 1, 2, 3, and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a.) Claim 1 recites "statistical evaluation". It is unclear what is meant by statistical evaluation. Does Applicant mean evaluation of numbers, diagrams, fluorescence? Clarification is required.

b.) Claim 2 recites "wherein the use of prostate-specific antigen (PSA), cytokeratin and/or epithelial membrane antigen as said selected antibody/ies". It is unclear what "use" Applicant is referring to. The claim language is hard to

follow and unclear. Does Applicant mean the selected antibody will be used in the intracellular staining of said cells in Claim 1? Applicant needs to clarify language of the claim to clearly point out the subject matter which the applicant regards as his invention.

c.) Claim 3 recites "wherein histogram analysis of the isotype control and staining after carrying out flow cytometry". The claim language is unclear and seems to be missing a few words. If Applicants' intention is to perform "histogram analysis of the isotype control and staining" after performing flow cytometry, the claim language should be re-written to distinctly claim that which applicant regards as his invention.

d.) Claim 6 recites an "analysis arrangement" of carrying out said method of Claim 1. It is unclear what is meant by the terms "analysis arrangement" and the specification does not provide an adequate definition. The claim limitations read on a kit comprising means for performing the method of Claim 1 and will therefore be examined as such.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Brandt et al. (Cancer Research, Vol. 56, pp.4556-4561, 1996).

8. The claims are drawn to a method and a composition for determination of characteristics and/or classification of circulating macrophages and/or peripheral mononuclear blood cells comprising the steps of taking a whole blood sample subjecting it to gradient centrifugation for isolating macrophages and/or peripheral mononuclear blood cells, perforating said cells and staining with a PSA antibody, followed by flow cytometric analysis for statistical evaluation of the cell contents.


9. Brandt et al. teach isolation of prostate-derived single cells and cell clusters from human peripheral blood. Brandt et al. teach a cytokeratin immunomagnetic method of isolating PSA-positive epithelial cells from the circulating blood of prostate cancer patients as a means to analyze genetic and biochemical characteristics of such cells for clinical relevance of prostate cancer cell identity and risk of metastasis (see p.4558 last paragraph and p.4561 last paragraph). Peripheral blood samples from patients were gradient centrifuged (see materials and method p.4556, right column, lines 30-31) and permeabilized using saponin (see materials and method p.4556 line 49) after which they were stained with antibodies directed to PSA, CD45, or CD14 (see p.4557 right column, lines 9-13). Flow cytometric analysis was then performed to sort the cells (see Fig. 1, p. 4558). The reported isolation method yielded prostate-derived cells or clusters of them from prostate cancer diagnosed patients (see Abstract). Specifically flow cytometric analysis revealed PSA-positive stained leukocytes (which include monocytes and macrophages) in the peripheral blood of patients (see p.4557, right column, 2<sup>nd</sup> full paragraph). The reference teaches each and every limitation of the claims.

**Conclusion**

10. Claims 1-6 are rejected.
11. No claim is allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meera Natarajan whose telephone number is 571-270-3058. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MN

  
LARRY R. HELMS, PH.D.  
SUPERVISORY PATENT EXAMINER